EXHIBIT 29

TO: Matthew P. Moriarty, Tucker Ellis and West LLP

Date: 09 December 2010

Subject: Review of Digitek Documents

Mr. Moriarty,

Per your request, I have reviewed the documents listed in appendix A to determine if there is evidence of release of double thick or tablets of variable dosage to consumers. Based on my review of the documented evidence presented, there is no evidence that double thick tablets or tablets of variable dosage strengths were released to the consumer.

Qualifications

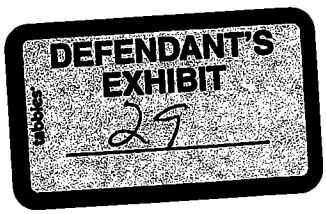
I am a consultant with 20 years experience in industry regulated by the U.S. Food and Drug Administration (FDA). I began my career as a Consumer Safety Officer with the FDA, and worked as an investigator in the Atlanta District of the FDA for 8 years. In this role, I audited finished dosage pharmaceutical manufacturers, including solid oral dosage manufacturers. After leaving the FDA, I worked as a consultant for pharmaceutical and medical device companies, including several large pharmaceutical companies who manufactured solid oral dosages. I also worked as a Director of Compliance of two large medical device manufacturers, Baxter Healthcare and Kimberly-Clark Healthcare. I have spent my career both evaluating drug and device manufacturer's compliance with FDA requirements, and in assisting companies to interpret and comply with FDA's current requirements and expectations.

FDA Experience

During my experience with the FDA, I led, and participated in, hundreds of audits and inspections of companies regulated by the FDA. I have issued numerous FDA Form 483's and written Establishment Inspection Reports (EIR) for these audits. Companies were issued Warning Letters based on my findings and work. My inspections also resulted in several seizures of products found to be adulterated or misbranded. I was also a member of the foreign inspection cadre, where I conducted inspections of regulated companies in Europe. I was promoted to District Automated Systems Specialist Investigator. I also detailed as acting Supervisory Consumer Safety Officer, and as acting Compliance Officer.

Consulting Experience

During my experience as a consultant, I consulted with pharmaceutical and medical device manufacturers to prepare them for inspection by the FDA, assisted clients in responding to 483's and Warning Letters issued by the FDA, and developed corrective actions based on audit findings by the FDA. I developed corrective action plans for firms under injunction or that have entered into consent decrees with the FDA. In addition, I developed and executed validation protocols and developed procedures. I also developed and conducted training on manufacturing and cGMP systems.



Industry Experience

During my experience as a Director of Compliance for Baxter Healthcare and Kimberly-Clark Healthcare, I developed audit procedures and created audit schedules, and directed auditors in conducting audits of internal and external manufacturing sites. My role was to ensure that all facets of these companies were in compliance with the requirements of the FDA and ISO.

Background of Process Validation

Validation of the manufacture of Digoxin was performed by Amide Pharmaceutical, Inc. (which later became Actavis Totowa, LLC). FDA requires finished dose pharmaceutical manufacturers to perform process validation prior to permitting them to distribute drugs in interstate commerce. Validation is a process accepted by the FDA as a means to provide confidence in the manufacture of products, including the manufacture of finished pharmaceuticals, when it is impossible or impractical to perform complete testing on a finished product. In these cases, testing all finished products for all quality attributes would be destructive and leave no saleable product for distribution.

For example, a tablet maker could not test every tablet manufactured for impurities or for potency as this would require dissolving the entire product to look for any impurities hidden within the tablets. As such, FDA and the life science industry has accepted the concept that it is possible to demonstrate, with a high degree of assurance, the consistent manufacture of product with a specified safety, quality, identity, potency and purity by using qualified equipment, validated processes, written procedures, and employees with proper training.

FDA has issued the "Guideline on General Principles of Process Validation," (May 1987), and the Global Harmonization Taskforce has issued "Quality Management Systems - Process Validation Guidance," (GHTF/SG3/N99-10:2004), to provide guidance to the pharmaceutical industry on recommended methods for validating manufacturing processes. While these documents do not establish legal requirements for validation, they were developed at the request of the life science industry to provide recommended best practices for the industry. These guidance documents recommend that: a.) specific documented evidence be established to demonstrate that the equipment is suitable for their needs; and b.) manufacturing processes are capable of consistently producing quality products. This documentation includes the establishment of final product and in-process specifications, equipment Installation Qualification (IQ), equipment Operation Qualification (OQ), and Performance Qualifications (PQ). IQ requires that manufactures establish that the equipment has been installed properly according to pre-determined specifications. IQ also establishes that critical measuring equipment has been calibrated, and that written procedures have been established covering the set-up and maintenance of the equipment. OQ establishes that the equipment functions according to predetermined requirements. OQ establishes that the equipment chosen for the job is capable of operating at the full range established in the manufacturing batch record within the environment in which it has been installed. PQ carries this further by establishing that the equipment and process performs consistently, by recommending the successful manufacture of three consecutive manufacturing batches. Product manufactured in these three batches is tested and scrutinized at a level higher than is expected during normal production batches.

The successful completion of the IQ, OQ, and PQ establishes, with a high degree of confidence, that the equipment and process used to manufacture product can consistently manufacture product meeting specifications. Since PQ requires successful execution of batch instructions using properly trained employees, the effectiveness and adequacy of the training and the adequacy and detail of the batch instructions is therefore demonstrated.

Digitek Process Validation

Review of the 0.125 mg and 0.25 mg Digitek Process Validation Reports provide documented evidence that the equipment and processes are capable of consistently manufacturing product meeting in-process and final product specifications. This documentation establishes that Amide/Actavis is capable of: a.) successfully blending the active ingredient and excipients into a homogenous mixture (as established through blend uniformity); and b.) then compressing that mixture into tablets that are consistently within established specifications for assay, weight, thickness, hardness, content uniformity, and dissolution, appearance, and friability. Amide performed four (4) validation studies to demonstrate their confidence in their ability to manufacture this drug. Below is a review of the four validation studies.

Review of the Digitek Process Validation Report Digoxin 0.125 mg Tablets, labeled as ACTAV 001866996-001867086, demonstrated that Amide Pharmaceuticals/Actavis Totawa successfully validated the process for manufacturing 1.6M tablet batches of Digoxin. The process and equipment Amide validated were transferred to Actavis. Blend Uniformity was demonstrated in both the 3 cu. ft. (blender #32) and the 10 cu. ft. (blender #35). This was demonstrated by the sampling and testing of each blend in the 10 cu. ft. blender at eleven pre-determined locations distributed both horizontally and vertically within the blender. This sampling was conducted over three consecutive blends. These samples were taken after blending operations were completed and were taken from pre-determined locations in the blending vessel to demonstrate the active ingredient was equally blended throughout the blending tank. Assay performed on these samples showed a high degree of uniformity, as all met percent label concentrations specifications. These had a standard deviation of 1.0, 1.5, and 1.0, for final blend assay to percent of labeled content.[1] This establishes that the blending process performed during this validation is capable of consistently creating a homogenous blend.

The blended drug was then compressed into tablets using a Stokes 45 station tablet press. In-process samples were collected every thirty minutes and tested for appearance, weight, thickness, and hardness. In addition, samples were taken at the beginning, middle, and end of the batch and tested for friability and dissolution. All samples were analyzed and found to be compressed within all specifications. This provides evidence that the press was set-up correctly, and continuously performed

[1] Standard deviation is a statistical method for determining the variability of the data is. A bell curve with a standard deviation of 1 presents itself as a very tight peak. Based on normal distribution, 68% of all results will be within plus or minus 1% of the mean, and 99.73% would be within 3 percent of the mean. A bell curve with a standard deviation of 1.5 would present as a somewhat less tight curve, meaning 68% of the data would be within 1.5% of the mean, and 99.73% would be within 4.5% of the mean. A process with a standard deviation of three means data is more widely distributed around the mean than a process with a standard deviation of 1.

within specifications. This type of surveillance of the press process is necessary for all types of presses, regardless of the make, model, or age of the press.

Samples were also collected throughout the production run and tested for Content Uniformity. This test demonstrates that tablets throughout the batch have a uniform concentration of active ingredient. Content analysis showed that all tablets met specification for label content and demonstrated a relative standard deviation of 1.2. This establishes that the tableting process is capable of consistently manufacturing tablets with their purported quantity of active ingredient.

Testing for the active ingredient in the Digoxin tablets was performed via a United States Pharmacopoeia (USP) established method using sample sizes specified in the USP method. The USP has established a reliable method for performing content analysis on products containing Digoxin as their main active ingredient. Since this method used by Amide/Actavis is an USP approved method, the FDA does not require Amide/Actavis to validate their HPLC method. This means that the FDA recognizes methods established by the USP as being accurate, reliable, robust, and precise enough for use in the testing of pharmaceuticals.

Amide Pharmaceuticals, Inc., Process Validation Report for Digoxin Tablets 0.125 mg, 1,600,000 Tablets, MPR No. 14502, was also reviewed. This validation report establishes that the Stokes 45 station press can be used at speeds of 14 - 28 rpm in the manufacture of Digoxin Tablets. The validation documentation supports the manufacture of tablets at this speed.

Amide Pharmaceuticals, Inc., Process Validation Report for Digoxin Tablets 0.125 mg, 4,800,000 Tablets, MPR No. 14504-01, was also reviewed. This validation report establishes that batch sizes of up to 4.8 million tablets can be successfully and consistently manufactured. The validation documentation supports the manufacture of tablets at this speed.

Review of the Digitek Process Validation Report Digoxin 0.25 mg Tablets, labeled as ACTAV 001867087-001867194, demonstrated that Amide Pharmaceuticals successfully validated the process for manufacturing 4.2M tablet batches of Digoxin. Blend Uniformity was demonstrated in the 3 cu. ft. (blender #32), the 10 cu. ft. (blender #35), and the 56 cu. ft. blenders (blender #22). Assay performed on these samples showed a high degree of uniformity, as all met percent label concentrations specifications. These had a standard deviation of 0.8, 1.1, and 1.3, for final blend assay to percent of labeled content. This establishes that the blending process performed during this validation is capable of consistently creating a homogenous blend.

Samples were also collected throughout the production run and tested for Content Uniformity. Content analysis was performed and found that all tablets met specification for label content, and demonstrated a combined standard deviation of 1.6. This establishes that the tableting process is capable of consistently manufacturing tablets with their purported quantity of active ingredient.

FDA also requires that pharmaceutical manufacturers routinely and periodically verify the performance of the tablet compression equipment by sampling and testing tablets throughout the tablet compression step. These tablets are tested for weight, appearance, thickness, and hardness. These are key quality

indicators used in the pharmaceutical industry to monitor the performance of the tablet press. If these key indicators remain within specification and the blend being fed to the tablet press is uniform, tablets will demonstrate consistent content uniformity, meaning each tablet will consistently contain the specified amount of active ingredient. Review of the process validation demonstrated that appropriate in process samples were collected and analyzed, and all results were found to be within specifications.

The batch records used to establish the three consecutive batches required for PQ were also reviewed for detail, clarity, and compliance with FDA's current expectations. My review did not reveal any deviations from the protocol, nor were there any production or quality issues identified. This evidence supports the conclusions made by executive management at Amide Pharmaceuticals that the process used to manufacture 0.125 mg and 0.25 mg Digoxin tablets is robust, capable, and consistent.

Review of Annual Product Reviews and Annual Reports

I also reviewed Annual Product Reviews and Annual Reports with Attachments for 2003-2008. Annual Product Reviews and Annual Reports created by Amide/Actavis for Digoxin tablets for 2003 through 2008 were reviewed. This review demonstrated that Amide/Actavis consistently manufactured Digitek meeting all final product specifications, including assay and content uniformity. All blend uniformity results and content uniformity results were well within specifications or expectations, demonstrating a process capable of consistently meeting specifications year after year.

Review of Batch Record for 70924A1

A review of the batch record 70924A1 (ACTAV 000002560-000002842), manufactured by Actavis Totowa, also demonstrated that blend uniformity testing was performed after the completion of the blending operation, and results met specifications.

During the manufacture of lot 70924A1, the operators sampled ten (10) tablets every thirty minutes from each of two press chutes per tablet press for these key quality indicators. These tablets were manufactured on a Stokes BB2 45 station press. These physical attributes of the tablets are tested contemporaneously within the same room as the tablet compression equipment. A thirty minute sampling interval is typical for successful monitoring of a tablet press. Results of the in-process sampling and testing demonstrated consistent tablet production by the two Stokes BB2 45 station machines. All in-process samples were found to be within specification for weight, appearance, thickness, and hardness.

There was also a QA overcheck performed every hour during compression. This is performed in addition to the QC in-process testing, and is part of the normal, in-process Quality testing. The QA overcheck verifies appearance, thickness, hardness, and weight. All results for this batch were verified to be within specification.

After the successful compression of the blend for lot 70924A1, samples of tablets were sent to the QC lab for further analysis of the final product. These samples were taken at random time intervals to ensure that the product meets final product specifications. Included in the final product testing is an

assay for the active ingredient using a USP HPLC method. Results for lot 70924A1 indicated the tablets were 96% of the labeled strength of 0.125 mg of the active ingredient, where the specifications were 90% to 105% of label claim.

A key aspect for ensuring consistency in manufacture is to establish complete and unambiguous operating procedures and batch records. Batch records should detail all operations necessary for the manufacture of products and include instructions for the correct equipment settings. Review of the batch record for 70924A1 demonstrated very clear and unambiguous instructions for the manufacture of product and for the correct set up of the compression and mixing equipment. The batch record appears completely filled out, and there is no indication the information was not entered contemporaneously. There is no indication that this data lacks integrity.

During the packaging of batch 70924A1, a packaging line operator identified two tablets that appeared to be over the normal tablet thickness. Packaging was halted, and management was notified. The remainder of the unpackaged product was examined, and one additional double thick tablet was identified in bucket 17, and two more were found in bucket 34. Management then decided to expand the investigation to determine if other double thick tablets had been packaged. Previously packaged product was unpackaged and inspected for double thick tablets. All tablets associated with batch 70924A1 were visually inspected to identify and cull any double thick tablets. Fifteen (15) additional double thick tablets were identified and culled, bringing the total number of double thick tablets identified to twenty (20). After all the double thick tablets were culled, the batch was packaged and released for distribution.

A review of investigation 07-093 revealed the firm performed an adequate investigation into the issue that caused double thick tablets. FDA's expectations for completion of a thorough investigation include the development of a scientifically based investigation, the establishment of one or more probable root causes, and the development of corrective actions based on the root cause identified. Documented evidence indicates that a fact based investigation was conducted, and that a potential root cause was identified. This root cause was based on the data available through interviews with personnel, and from a review of the batch record and analytical testing records. The investigation was begun immediately upon discovery of the event, while it took several weeks to piece together all of the elements of the investigation. While the determination of the actual root cause is not always possible after an event, the root cause for the creation and release of double thick tablets appears plausible and probable.

This investigation conducted was typical of the level and depth normally conducted by pharmaceutical companies during non-conforming product investigations.

There is no indication from the investigation that these tablets appeared to be "capped," meaning that a tablet was processed through the tablet press a second time to produce a tablet that appears to be a second tablet added on top of a fully formed tablet. This would eliminate the hypothesis that the double thick tablets were formed by failing to be ejected after compression. There is also a "QA In-Process Compression Start Up Data Sheet" (page 16-19 of 67 within 07-093) that indicates that the output or tablets from all 45 strokes from the Stokes tablet presses were verified to be within weight

and thickness. This test was also performed after press #67 was disassembled, cleaned and restarted. All tablets were found to be within specification after start up. This means that the equipment was properly adjusted, and that there were no punches that were too short. Since the press is set up correctly and is ejecting tablets, only two possible causes for double thick tablets remain. The first is that the equipment adjustments were not tightened sufficiently, allowing the press to drift away from the adjustments established during press set-up. This is not a likely cause for the double thick tablets because this drift would be detected during the in-process sampling taken every thirty minutes during production. This would have been detected in an upward drift in tablet thickness, meaning tablets would be measured to be getting thicker.

Because of the manner in which tablet presses operate, it would not drift into manufacturing thin tablets without manual adjustment of the press by an operator. Evidence of this type of adjustment was not found within the batch record for 70924A1, making this an unlikely root cause. This leaves the most likely root cause of the double thick tablets, being an error during clearance of the equipment after set-up.

During set-up of a tablet press, the operator adjusts the punch depth on a running press in order to create tablets meeting specifications. Once equipment set-up has been completed, the operator requests QA to confirm that the press is making tablets meeting specifications. This is confirmed using the "QA In-Process Compression Start Up Data Sheet," mentioned above. After QA confirms proper set-up, the equipment is released for production of marketable tablets. However, before asking for confirmation from QA, the operator must clear the line of all the tablets that were created during set-up, which could include product that is above the tablet thickness specifications (i.e. thick tablets). If this is not performed properly or completely, thick tablets may be left in the process line, and may end up in finished product.

The documentation provided during the investigation supports the root cause proposed by Actavis management and documented in Investigation 07-093. Improper line clearance after equipment set-up appears to be the most likely root cause given the information provided. Based on this root cause, visual inspection of the product is a viable method for correcting this type of defect. Since this defect is easy to visibly identify, it was likely that a visual inspection of the product would have resulted in the identification and culling of double thick tablets. Additional, post-culling inspection was performed on the batch to ensure the culling process was capable of successfully removing any double thick tablets. No additional double thick tablets were found during this additional inspection process. Once the culling had been successfully performed, the decision to release of 70924A1 appeared justified based on my review of the investigation and the batch record.

The investigation appears complete, and was performed as well as can be expected given the retrospective nature of the investigation. The conclusions appear sound and seem to fit the documented evidence provided. This also means that the number of double thick tablets produced was very small, and were successfully culled from the batch. The root cause identified appears the most plausible.

Review of Third Party Analytical Testing

Data from stability testing performed by third party laboratories for UDL Laboratories, Inc., 1718 Northrock Ct., Rockford, IL, was also reviewed (Exhibit 83 UDLL 000011361-000011401 and Exhibit 84 UDLL 000011291). This test data covered the stability of selected Actavis (Amide) Digoxin 0.125mg and 0.25mg Digoxin lots manufactured from February 1999 through September 2007. Not all lots manufactured by pharmaceutical companies are placed on stability testing. However, the FDA requires at least one lot per year be placed on stability, and any lots subject to significant changes be placed on stability. More than thirty-three (31) lots were included in the data provided by UDL Laboratories. All lots tested for each time interval were found to be within specification for assay and dissolution.

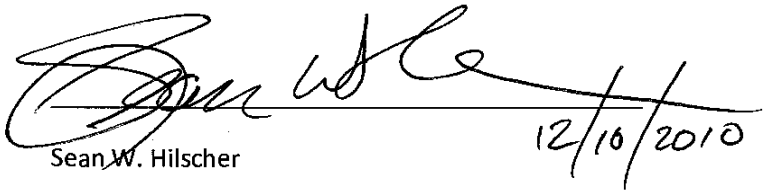
Review of analytical results provided by the US FDA for samples of Digitek (Digoxin) tablets collected as part of routine surveillance sampling demonstrated all results presented found the products to be within specification for identification, dissolution, and content uniformity. Batches included in this survey were:

- 0.25mg Digoxin, Lot 8A332, expires 07/09
- 0.125mg Digoxin, Lot 70737A1, expires 09/09
- 0.125mg Digoxin, Lot 70298A1, expires 04/09
- 0.125mg Digoxin, Lot 7P964, expires 04/09
- 0.25mg Digoxin, Lot 70811A1, expires 10/09
- 0.25mg Digoxin, Lot 706641A1, expires 08/2009
- 0.125mg Digoxin, Lot 70078A1, expires 01/09
- 0.125mg Digoxin, FDA Sample 157503
- 0.125mg Digoxin, FDA Sample 157504

Third party testing for assay and content uniformity did not reveal any tablets or batches that were out of specification. Celsis Analytical Services, 6200 S. Lindberg Blvd., St. Louis, MO 63123, performed testing on three batches of Digoxin, lot numbers 61097A1, 60992A1, and 61100A1. These results found all lots tested to be within specification for appearance, assay and dissolution. The RSD for the three batches were 1.27%, 1.4%, and 0.83%.

Conclusion

From review of the validation documentation and the batch records presented, there is no evidence that double thick tablets or tablets with variable assay content were released to market.



12/10/2010

Sean W. Hilscher

Consultant, Pharmatech Associates, Inc.

Appendix A

Documents Reviewed

- Annual Data/Product Reviews (APR) with Attachments for 2003-2008
  - APR 2003 (ACTAV 000005279-0000005657)
  - APR 2004 (ACTAV 000005687-0000006026)
  - APR 2005 (ACTAV 000006042-0000006145)
  - APR 2006 (ACTAV 000006201-0000006436)
  - APR 2007 (ACTAV 000006489-0000006568)
  - APR 2008 (ACTAV 001310391-001310507)
- Digitek Process Validation Report Digoxin 0.25 mg Tablets (ACTAV 001867087-001867194)
- Digitek Process Validation Report Digoxin 0.125 mg Tablets (ACTAV 001866996-001867086)
- Batch Record 70924A1 (ACTAV 000002560-000002842)
- Batch records for 70770 (which had interim out of specification result in the Blend Uniformity Stage)
- Batch records for 70836 (Immediately before Batch 70924A)
- Batch records for 70925 (Immediately after Batch 70924A)
- Batch records for 70207
- Batch 80226
- Batch 80228
- Batch 70148
- Batch 80228
- UDL/Celsis stability data (Exhibit 83 UDLL 000011361-000011401)
- Memorandum from Tom Spaine to Sue Powers, dated May 5, 2008, (Exhibit 84 UDLL 000011291)
- Amide Pharmaceutical, Inc., Process Validation Report, Digoxin Tablets, 0.125 mg, 1,600,000 Tablets, MPR No. 14502-00
- Amide Pharmaceuticals, Inc., Process Validation Report, Digoxin Tablets, 0.125 mg, 4,800,000 Tablets, Protocol 14504-01
- FDA 484 sample testing of 448881, 462753, 462746, 377410, 453913, 454866 and 448892
- 2004 FDA EIR
- July 2008 FDA EIR
- FDA Warning letters (dated 08/15/06; 01/09/07; & 02/01/07)
- FDA Form 483's (dated 02/08/06; 08/10/06; & 05/20/08)
- Recall Notice
- Celsis documents concerning Mylan testing
- Gibraltar Laboratories documents
- Quantic Regulatory Services summary of batch record review
- Investigation report dated 07/09/04, labeled as Pltf's Exh #128, and docs relating to complaint from Rite Aid pharmacist in May 2004